Panel Discussion

PANEL DISCUSSION

OPENING REMARKS FOR PANEL DISCUSSION ON GUIDE - LINES FOR USE OF HUMAN CADAVERS IN SAFETY RESEARCH

The past year has been a trying year for many of us involved in bio-mechanical research through the use of human cadavers. The federal governments stop order remained in effect for most of the year. Then, during the summer there were congressional hearings about cadaver usage. The situation has been bad and good. The bad aspect of the stop order was the cessation of work which was felt to be valuable and which was felt would help save some lives. The good aspect of it is that it has forced those involved to look at research programs and to look at the use of cadavers. It has been a year of introspection and questioning. This panel is partly to answer some of those questions which have arisen during the past year.

One question which I hope the panelists will answer is that of the ethics of cadaver usage. Most of the cadavers are donated to the universities for research. Questions have been asked as to the exact interpretation of the donation. Some feel that a special consent should be obtained for the use of the cadaver in impact studies. In some states there are laws which may make this difficult or impossible.

The question of cadaver standards is another major problem. What is the effect of rigor mortis on cadavers? Should the cadaver be used prior to the ending of post-mortem rigor or is it safe to use to use the cadaver during the peak period of rigor. After the cadaver is tested, how should the autopsy be performed? Is it necessary for a trained M.D. such as a pathologist or traumatologist be present and perform the autopsy or can engineers and other researchers be trained to perform a satisfactory

autopsy and obtain all necessary data? Should there be a protocol for autopsies or should the autopsy procedures be tailored to the project.

We will have each panelist make some opening statements. After the opening statements we will have time for questions to the various panelists. I realize that we are a relatively small group but I think it would expedite the panel if we could have your questions written and passed forward. This would allow me to group similar questions so that the discussion could proceed along some sort of course rather than moving randomly through topics of which some are closely related and some are distally related. Some of you may wish to make statements or comments. I will allow time for these after coffee. Please send up a note indicating your desire and the topic so we can arrange them in some sort of an order. I believe that all of the panelists are well known to you.

Our first speaker will be:

A NARRATIVE DETAILED DESCRIPTION OF THE ACQUISITION PROCESS FOR OBTAINING CADAVERA USED IN AUTOMOTIVE SAFETY RESEARCH AT CALSPAN CORPORATION'S ADVANCED TECHNOLOGY CENTER

By: Michael J. Walsh
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Prepared For:

Panel Discussion On Guide-Lines
For the Use of Human Cadavers
In Safety Research

Presented At The
Sixth Annual International Workshop On
Human Subjects For Biomechanical Research

October 23, 1978

Ann Arbor, Michigan

INTRODUCTION

It must be understood at the outset that neither the human volunteer, the cadaver nor the ATD are, by themselves, sufficient human surrogates for the complete range of automotive occupant protection research. All three, judiciously applied, are required to obtain the information needed to design and develop restraint systems and to evaluate their effectiveness.

One of the obvious and proper uses of the volunteer and the cadaver is to allow for the current ATDs to be anthropomorphized to a higher degree. By definition this can only be accomplished through research using volunteers and cadavera.

It is unlikely that ATDs will ever attain a level of bio-fidelity to be considered the ultimate human surrogate. Their role is seen as that of a repeatable device for demonstrating performance evaluation criteria as opposed to the role of demonstrating injury evaluation criteria. Since human volunteers cannot be subjected to potentially injurious exposures, the roll of demonstrating injury producing mechanisms necessitates the use of cadavera.

Clearly, the use of cadavera cannot be incorporated into a performance standard subject to compliance testing. Too much variability exists in cadaver subjects to allow this. The cadaver is best used to supplement the performance evaluation data obtained from the ATDs with injury evaluating data in the design and development of restraint systems.

Finally, the argument can be made, and often is, that the cadaver is overly sensitive to the crash environment especially when concentrated loadings are involved and that a healthy live subject would not experience a similar extent of injury. However, an argument cannot be presented which would state that the effects of load concentration vividly displayed in the cadaver autopsies are not undesirable or not worthy of attention. It follows that demonstration of the effectiveness of a restraint system, with regard to injury producing mechanisms, can only be accomplished by the use of cadavera.

Cadavera used in automotive safety research at the Advanced Technology Center of Calspan Corporation are supplied by, and returned to, the Department of Anatomical Sciences of the State University of New York at Buffalo. The subjects have been previously willed to the University for use in medical and scientific research either by the subjects themselves or their next of kin. In addition, a personal interview with the next of kin is conducted by the Principal Investigator from Calspan and a representative of the University. During this interview the objectives and techniques of the program are briefly explained and a release document for the use of the body in this research is signed and witnessed. A licensed mortician (from the University) is directly involved throughout all phases of each test in accordance with the requirements of the applicable laws of the State of New York (1)*. Further, at least one licensed physician is on site for each test involving the use of a cadaver. Final disposition of the cadavera used to date has been by cremation, as directed in the willing documents, with the ashes being distributed to the next of kin if so desired.

DISCUSSION

The selection process for acceptance of cadavera as test subjects for automotive safety research is a multi-faceted one which includes the next of kin interview. A short background on this process seems to be an appropriate starting place for this detailed description.

The time from death of a potentially usable subject to the actual test date must be kept to the shortest interval possible, commensurate with the required preparation of both the cadaver and the test vehicles. Upon notification from the University of a cadaver's availability, the death certificate is reviewed for the subject's age, cause of death and assurance

*Numbers in parentheses designate references at the end of the discussion.

that no infectious diseases have been diagnosed. This review is followed up by a telephone conversation with the attending physician (when possible) and/or the hospital records office (when applicable) for confirmation of the information on the death certificate and for indication of the length of bed confinement of the subject prior to death. Anthropometry measurements are also obtained at this time, and a palpation examination is performed by the medical monitor.

The Contract Technical Monitor (CTM) is then notified, by telephone, and the pertinent information on the subject is relayed to him for the NHTSA's review and preliminary agreement for the use of the cadaver in a crash test. Upon preliminary approval by the CTM an appointment is made for an interview with the next of kin, preparations of the crash test vehicles are initiated and preparations are made for the pre-test x-ray studies of the subject.

Calspan Corporation has conducted a total of 21 automotive safety related tests using 19 cadavers between the dates of March 12, 1975 and August 11, 1977. In keeping with the requirements of the "Resolution Concerning Ethical Position on the Use of Human Bodies in Research," (2), with regard to subject anonymity, Calspan devised a generic word "Calman" to designate the cadavera. This word is followed by a serial number, i.e., Calman 1, Calman 2, etc.. Calman 6 and Calman 7 were exposed to two tests each (Calman 6A and 6B, Calman 7A and 7B) thereby accounting for the 21 tests with 19 cadavers.

All 19 cadavers used in these tests were bodies that had been willed to the University. With the exception of Calman 13 and Calman 19 (willed by the next of kin) all had been self-willed. There have been no unclaimed (indigent) bodies used at Calspan.

Starting with Calman 14, who died on June 20, 1977, it was decided that an informed consent document (sample included as Attachment A) from the next of kin should be required for the use of a cadaver in automotive safety research in addition to the willing documents on record at the University

(sample included as Attachment B). This decision was made between the Head of the Department of Anatomical Sciences at the University and the Principal Investigator at Calspan.

As stated earlier the appointment for the interview is made after preliminary approval for use of the subject by the CTM. The details of this interview are described below.

The Principal Investigator from Calspan contacts the next of kin of the deceased by telephone and makes an appointment for an interview, at a time and place determined by the wishes of the next of kin. They are told that it is our desire to explain a research program to them and to obtain their signature on an additional document.

At the appointed time and place representatives from Calspan and the University explain that we are conducting research in the field of automotive safety. They are told that the makeup of this research team consists of engineers, engineering technicians, medical doctors, medical technicians and faculty and staff of the University. It is explained that these tests will be conducted in standard automobiles (in these specific cases) utilizing either production air cushion restraint systems or production belt restraint systems (whichever happens to coincide with the scheduled test) and that the subject will not be subjected to an unrestrained crash situation. They are informed that the subject will be instrumented with force, pressure and acceleration sensing devices and that he/she will be x-rayed and an autopsy will be performed.

The objectives and purposes of these federally funded tests are described. It is explained to them that the decision is theirs to make by free choice and whatever their decision is, it will be strictly adhered to by both Calspan and the University. There is never an attempt made by either representative to "sell" the program to the next of kin. All questions that

are asked are answered openly and honestly to the best ability of the Principal Investigator and the University representative.

If the next of kin decide that the body may be used for the research program described they sign the release form (Attachement A) and their signature is witnessed. In most cases these witnesses have been family members or family friends of the deceased or next of kin. When there have been no additional family members or friends present, the witnesses have been the representatives from Calspan and the University.

If the next of kin decide against the use of the body in the research program described, there is no signing and the interview is concluded with the assurance to the next of kin that their wishes will be honored. All test preparations are halted and the cadaver is prepared for use in and by the University.

REFERENCES

1. "Laws, Administrative Rules and Regulations Relating to Funeral Directing," New York State Department of Health, Revised January 1, 1974.

2. "Resolution Concerning Ethical Position on the Use of Human Bodies in Research," Third Annual International Workshop on Human Subjects for Bio-Mechanical Research, held in San Diego, California, November 1975.

Michael J. Walsh

Michael J. Walsh
Principal Investigator
Transportation Research Department

Attachment A

I, the next of kin of _____
(name of donor)

of _____, _____, who having heretofore
(city) (state)

by will or other properly executed document donated (his)/(her) body to

_____ for purposes of medical-
(name of institution)

study and scientific research do agree that the body may be used for automotive safety research.

Signature _____

Address _____

Date _____

Witnesses: _____

_____

Attachment B

STATE UNIVERSITY OF NEW YORK AT BUFFALO—SCHOOL OF MEDICINE
DEPARTMENT OF ANATOMICAL SCIENCES
BUFFALO, NEW YORK 14214
Telephone: 831-2912 Night No. 834-8128

I hereby direct that my body be delivered, after my death, to the Medical School of the State University of New York at Buffalo for purposes of medical study and research; that such delivery be made as soon as possible, without embalming, or autopsy.

SIGNATURE .....

ADDRESS .....

DATE .....

WITNESSES:

.....

.....

KEEP THIS COPY

STATE UNIVERSITY OF NEW YORK AT BUFFALO—SCHOOL OF MEDICINE
DEPARTMENT OF ANATOMICAL SCIENCES
BUFFALO, NEW YORK 14214
Telephone: 831-2912 Night No. 834-8128

I hereby direct that my body be delivered, after my death, to the Medical School of the State University of New York at Buffalo for purposes of medical study and research; that such delivery be made as soon as possible, without embalming, or autopsy.

SIGNATURE .....

ADDRESS .....

DATE .....

WITNESSES:

.....

.....

GIVE THIS COPY TO YOUR NEXT-OF-KIN, ATTORNEY, OR PHYSICIAN

STATE UNIVERSITY OF NEW YORK AT BUFFALO—SCHOOL OF MEDICINE
DEPARTMENT OF ANATOMICAL SCIENCES
BUFFALO, NEW YORK 14214
Telephone: 831-2912 Night No. 834-8128

I hereby direct that my body be delivered, after my death, to the Medical School of the State University of New York at Buffalo for purposes of medical study and research; that such delivery be made as soon as possible, without embalming, or autopsy.

SIGNATURE .....

ADDRESS .....

DATE .....

WITNESSES:

.....

.....

PRINT LAST NAME HERE

RETURN THIS COPY TO THE DEPARTMENT OF ANATOMY, STATE UNIVERSITY OF NEW YORK AT BUFFALO, SCHOOL OF MEDICINE, BUFFALO 14, N. Y.

( ) Dispose of ashes ( ) Save ashes ( ) Roman Catholic

PLEDGED BODY

I _____ have donated to the School of Medicine, State University of N.Y. at Buffalo, Department of Anatomical Sciences, Buffalo, N.Y. 14214, immediately following death, my body for teaching purposes, scientific research or for such purposes as the University, or its authorized representatives, shall in their sole discretion deem advisable.

831-2912 (Monday-Friday; 8:30 A.M.-5:00 P.M.)
834-8128 (Nights, Saturday, Sunday, Holidays)

Date _____ Signature _____

Address _____

CALSPAN CORPORATION
Buffalo, New York 14225

ON THE SIMILARITIES AND DIFFERENCES BETWEEN HUMAN CADAVERS, HUMAN VOLUNTEERS AND ANTHROPOMETRIC TEST DEVICES USED IN CRASH TESTING

Michael J. Walsh

Presented At The

Sixth Annual International Workshop On
Human Subjects For Biomechanical Research

October 23, 1978

Ann Arbor, Michigan

OBJECTIVES

The objectives of this special report are to depict the similarities between the human cadaver and the human volunteer used in automotive safety research; to describe the lack of bio-fidelity in current anthropometric test devices (ATD); to show the similarities (where they exist) between the three; and to point out the need for continuing use of all three in the field of occupant protection research.

INTRODUCTION

This report includes a narrative description of an eight minute, 16 mm color film. With the exception of three scenes (17, 18 and 20) the film is made up of high speed (1000 PPS) data movies taken at Calspan Corporation's Advanced Technology Center. The first three scenes show work that was sponsored by Calspan and the above mentioned three scenes are film borrowed from the Allstate Insurance Company. The rest of the film depicts work that was sponsored by the National Highway Traffic Safety Administration (NHTSA).

It must be understood at the outset that neither the human volunteer, the cadaver nor the ATD are, by themselves, sufficient human surrogates for the complete range of automotive occupant protection research. All three, judiciously applied, are required to obtain the information needed to design and develop restraint systems and to evaluate their effectiveness.

One of the obvious and proper uses of the volunteer and the cadaver is to allow for the current ATDs to be anthropomorphized to a higher degree. By definition this can only be accomplished through research using volunteers and cadavera.

It is unlikely that ATDs will ever attain a level of bio-fidelity to be considered the ultimate human surrogate. Their role is seen as that of a repeatable device for demonstrating performance evaluation criteria as opposed to the role of demonstrating injury evaluation criteria. Since human volunteers cannot be subjected to potentially injurious exposures, the roll of demonstrating injury producing mechanisms necessitates the use of cadavera.

Clearly, the use of cadavera cannot be incorporated into a performance standard subject to compliance testing. Too much variability exists in cadaver subjects to allow this. The cadaver is best used to supplement the performance evaluation data obtained from the ATDs with injury evaluation data in the design and development of restraint systems.

Finally, the argument can be made, and often is, that the cadaver is overly sensitive to the crash environment especially when concentrated loadings are involved and that a healthy live subject would not experience a similar extent of injury. However, an argument cannot be presented which would state that the effects of load concentration vividly displayed in the cadaver autopsies are not undesirable or not worthy of attention. It follows that demonstration of the effectiveness of a restraint system, with regard to injury producing mechanisms, can only be accomplished by the use of cadavera.

In the discussion that follows the similarities and differences between the three surrogates will be displayed.

DISCUSSION

The first three scenes show a 50th percentile ATD and a human volunteer side-by-side on a test sled subjected to a 17 MPH simulated barrier crash. Both are restrained with identical 3-point lap belt and shoulder strap restraint systems. The sled pulse was of half sine wave shape with a peak acceleration of 12 G_x and a duration of 120 milliseconds. This is the highest known exposure of a human volunteer restrained by standard production lap and shoulder straps. The volunteer, as required by test protocol, wore a slack

belt system as a backup in case of failure of the primary restraint.

Instrumentation for the ADT included the standard head and chest triaxial acceleration measuring instruments as well as belt tension measuring load cells. Volunteer instrumentation was limited to three head accelerometers, electrocardiogram (for the medical monitor's evaluation) and belt load cells. No chest accelerometers were placed on the volunteer because of the potential for injury upon rebound. The volunteer rode in a non-braced condition attempting to simulate the "one g" settings used in ATD setup and testing.

Peak values of data obtained from this test were:

	Volunteer	ATD
Head Acceleration		
A-P	30 G	14 G
S-I	16 G	16 G
R-L	20 G	4 G
Resultant	35 G	19 G
Chest Acceleration		
A-P	N/M	13 G
S-I	N/M	7 G
R-L	N/M	2 G
Resultant	N/M	14 G
Belt Loads		
Right Lap	920	840 pounds
Left Lap	510	410 pounds
Shoulder	730	820 pounds

It is interesting to note that the sum of the volunteer lap belt loads divided by the sum of the ATD lap belt loads is 1.144. If the ATD weight (164 pounds) is multiplied by this factor the product (188 pounds) approximates the weight of the volunteer at the time of the test (186 pounds). Using this same multiplier for the shoulder belt loads the volunteer would have experienced a load of 835 pounds. This apparent anomaly was caused (as can be seen in the film, third scene) by the fact that the backup shoulder strap came into play during the test but only the primary shoulder strap loads were being monitored.

The primary differences between the volunteer and ATD results are seen to be in the kinematics of the two. Notice that the volunteer is much more compliant than the ATD. Both the head and shoulder motions of the volunteer are approximately double those of the ATD. In the front view it is seen that the volunteers upper thorax is wrapping around the shoulder strap while the ATD's upper thorax remains relatively flat; the ATD is being forced down in the seat while the volunteer is stroking more horizontally and the ATD is into rebound when the volunteer is still moving forward. The arms of the volunteer and the ATD do move similarly but this aspect of the kinematics are not considered germane to potential serious trauma.

Scene four shows a front view of a cadaver in an experimental belt restraint system test at 30 MPH on the same test sled. Notice that his compliance and kinematics are very representative of those of the volunteer in the previous scene.

Using the same restraint system and test conditions, scenes five through eight graphically show the differences between the cadaver and the ATD. Again, as was the case when the volunteer and the ATD were exposed to the same crash simulation, the cadaver is much more compliant than the ATD. The head and shoulders move in a greater magnitude, the upper thorax and shoulders wrap around the shoulder restraint and the rebound phase is symmetric for the cadaver while the ATD is spinning off to the right. The gross differences in rebound trajectory are apparent by comparing scene seven, the cadaver, with scene eight, the ATD.

There are two important points to be made from these sequences. The first is that while the cadaver and ATD instrumentation indicated a non-traumatizing exposure, e.g., chest resultant accelerations of 58 G's for the cadaver and 53 G's for the ATD (using the same instrumentation located at the same anatomical landmarks) the cadaver displayed potentially fatal injuries in the thoracic and abdominal regions at autopsy. The second point is that the kinematic differences notwithstanding, one cannot subject an in-vivo volunteer to this level of exposure and without the use of the human cadaver

these injury mechanisms could not be determined.

Demonstrating that the differences between cadaver and ATD responses are not limited to test sled exposures of crash simulations, scenes nine and ten are high speed movies of identical symmetric frontal car crashes in which each car was moving at 30 MPH. The same phenomena of head excursion, chest compliance and rebound of the cadaver versus the ATD are observed in these scenes as were apparent on the sled.

Probably the most noticeable differences between the reactions of cadavera and ATDs is presented in the movies of the higher speed (46 MPH) sled tests of scenes eleven through fourteen. As before, side views and rear views of the cadaver and the ATD are shown. On impact, the early stages of the test, the cadaver and the ATD move into and ride down the air cushion in a similar manner. On rebound however, the less compliant ATD leaves the seat and travels more upward and inboard striking his head on the head liner and roof. The cadaver, being taller than the ATD, overrides the cushion and strikes the head liner on impact (ridedown) and while the rebound phase shows him raising slightly off of the seat cushion, his direction, as seen from the rear view, is symmetric.

In these two tests the chest acceleration instrumentation used on both the cadaver and the ATD were in good agreement with regard to the resultant value, i.e., 57 G's on the cadaver and 59 G's on the ATD. The important aspect of this is that if one were to compare just the acceleration levels of these air cushion tests to those of the previously discussed belt test results it would be reasonable to expect thoracic and/or abdominal trauma at a life-threatening level. This was not the case; in fact, there were no injuries found at autopsy on this subject in the thoracic or abdominal regions. Again, injury producing mechanisms cannot be determined without the use of cadavera.

Returning to the discussion of the similarities between the cadaver and the in-vivo, scenes fifteen through twenty are movies taken of a cadaver as the driver of an air cushion vehicle in a symmetric frontal car-to-car

crash with each car moving at 30 MPH (scenes fifteen and nineteen), an ATD in the same type of crash (scene sixteen) and a stunt driver driving an air cushion equipped car into a reinforced concrete wall at 32 MPH (scenes seventeen, eighteen and twenty). These crash modes are very similar in their effect upon vehicles and occupants. It is seen that the cadaver, the ATD and the in-vivo (scenes fifteen, sixteen, seventeen and eighteen) ride down the air cushion in the same manner. Scenes seventeen and eighteen are the same film clips used twice because of the shortness in time duration (this was not taken with a high speed camera). The ATD rebounds in the opposite direction from the cadaver and its head comes very close to striking the B-pillar of the car. When viewed from the rear, scenes nineteen and twenty, it is observed that even though the in-vivo is bracing himself against the impact his kinematics are virtually identical to those of the cadaver. They both strike the headrest on the inboard side at approximately the same position.

CONCLUSIONS

1. The results of these experiments clearly demonstrate that testing with the use of cadavera should play a significant role in restraint system design, development and evaluation.

2. Specific cases were shown wherein ATD results were not capable of locating problem areas of restraint systems which were evident from, and only attainable by, the cadaver results.

3. Human volunteer, cadaver and ATD testing play complementary and supplementary roles in occupant protection research.

4. Human cadavera, even though they are devoid of muscle tonus respond to impact levels of the severity of serious automobile crashes in the same manner as a trained, well conditioned, braced in-vivo human subject.

GUIDELINE RECOMMENDATIONS USING EXTERNAL REVIEW PROCESS IN STUDIES INVOLVING WILLED HUMAN BODIES IN AUTOMOTIVE SAFETY

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ABSTRACT

In view of the recent public concern about the growing use of cadavers in automotive safety testing, it has been the opinion of General Motors Research Laboratories and Technical Staffs that in many aspects the intrinsic limitations of the data obtained on unspecified anatomical subjects do not provide immediately applicable and field-relevant information. It has been recommended that the usage of cadavers be restricted only to protocols where the expected benefit unquestionably justifies the usage of the willed human bodies obtained in accordance with the Uniform Anatomical Gift Act.

In May 1978, Research Laboratories voluntarily accepted a self-imposed policy requesting that in addition to the internal review, every protocol intending to use human cadavers must be recommended also by an extramural committee consisting entirely of representatives of academia and interested public groups. The committee established its own review procedures which are substantially equivalent to rules for review of programs involving human volunteers and include consideration of the minimum basic principles, i.e. that the donation of the willed bodies be in compliance with the Uniform Anatomical Gift Act and approved by the appropriate medical institution, that only subjects freely donated for medical research be utilized, that the need for cadaver usage be documented, that the reasons why currently available anthropomorphic dummies or other surrogates are not suitable be explained, that the human qualities of cadaver bodies be explicitly recognized by research personnel and treated with appropriate dignity and respect, and that the expected benefits to live human beings be substantially demonstrated in the protocol.